

CLAIMS

What is claimed is:

1. A method of monitoring gastric emptying in a mammal comprising:
 - 5 a. administering to said mammal a formulation comprising an agent that is formulated in a delayed-release formulation that prevents said agent from being released into the gastrointestinal tract when the pH of the gastrointestinal tract is lower than about 6.0, and
 - b. determining the amount of time taken for an elevated 10 concentration of said agent to be found in the blood of said mammal.
2. The method of claim 1, wherein the amount of time taken for elevated concentrations to be found in the blood of said mammal is greater than five minutes.
3. The method of claim 1, wherein said agent is an agent that is 15 not present in normal dietary substances.
4. The method of claim 1, wherein said agent is a sugar.
5. The method of claim 4, wherein said sugar is selected from the group consisting of D-xylose, D-galactose, D-mannose, D-fructose, L-fucose, L-rhamnose, and L-sorbose.
- 20 6. The method of claim 1, wherein said agent is selected from the group consisting of acetominophen, aspirin, caffeine, cephalosporins, beta-lactam antibiotics, cimetidine, ranitidine, famotidine, nizadidine, alprazolam, gentamicin, amikacin, vancomycin, diclofenac, ibuprofen, D- amino acids, beta carotene, ascorbic acid, sulfur dioxide, biotin, inositol, zinc, vitamin B12, folate, aluminum sulfate, eugenol, citral, vanillin, and malic acid.
7. The method of claim 1, wherein said agent is encapsulated in a pH-sensitive formulation.
8. The method of claim 1, wherein said agent is non-isotopic.
9. The method of claim 1, wherein said agent has been formulated 30 into a test meal.

10. A method of diagnosing a gastric emptying disorder in a mammal comprising:

- a. administering to said mammal a formulation comprising an agent that is not released into the gastrointestinal tract at a pH lower than about 6.0,
5 and
- b. determining the amount of time taken, post-administration, for an elevated concentration of said agent to be found in the blood of said mammal, wherein said mammal is diagnosed as having a gastric emptying disorder if said agent is not elevated in the blood stream 120 minutes post-administration.

10 11. A method of diagnosing gastroparesis in a human comprising:

- a. administering to said human a formulation comprising D-xylose that is not released into the gastrointestinal tract at a pH lower than about 6.0, and
- b. determining the amount of time taken, post-administration, for
15 an elevated concentration of said D-xylose to be found in the blood of said human, wherein said human is diagnosed as having a gastric emptying disorder if said agent is not elevated in the bloodstream 120 minutes post-administration,

wherein said human has previously been or is later determined not to have a blockage of the stomach or small bowel.

20 12. The method of claim 11, wherein the total dosage of D-xylose administered is between about 5 grams and about 25 grams.

13. A method of screening for a compound that modulates gastrointestinal motility in a mammal comprising:

- a. administering a test compound to said mammal;
- b. monitoring the effect of said test compound on gastric emptying by administering to said mammal a formulation comprising an agent that is not released into the gastrointestinal tract at a pH lower than about 6.0, and
25
- c. determining the amount of time taken, post-administration, for an elevated concentration of said agent to be found in the blood of said mammal in the

presence and absence of said test compound, wherein a test compound which alters the rate of gastric emptying is identified as a modulator of gastrointestinal motility.

14. The method of claim 13, wherein said test compound increases gastrointestinal motility as determined by an increase in the time from administration
5 to appearance of said agent in the blood of said mammal.

15. The method of claim 13, wherein said test compound decreases gastrointestinal motility as determined by a decrease in the time from administration to appearance of said agent in the blood of said mammal.

16. A modulator of gastrointestinal motility identified according to
10 the method of claim 13.

17. The modulator of claim 16, wherein said modulator is a prokinetic agent.

18. A formulation for determining gastrointestinal motility comprising between about 250 mg and 1000 mg of D-xylose and a pharmaceutically
15 acceptable carrier, diluent, or excipient.

19. The formulation of claim 18, wherein said formulation is prepared as a test meal.

20. A kit comprising the formulation of claim 18 and instructions for the performance of an assay for determining gastric motility.

21. The kit of claim 20, further comprising a blood collection device.

22. The kit of claim 20, further comprising a composition for detecting the presence of the marker agent.

23. The kit of claim 20, further comprising a second marker agent
25 formulated in a formulation that prevents said second marker agent from being released at a pH lower than about 6.0.

24. The kit of claim 23, wherein said second marker agent is formulated in the same delayed-release formulation as said first marker agent.

25. The kit of claim 20, further comprising a series of
30 concentrations of marker agent in delayed release formulations for use in producing a

standard curve, said formulations each being resistant to release of said marker agent at a pH lower than about 6.0.

26. The kit of claim 25, further comprising a reagent that lowers the pH of the formulation to a pH lower than about 6.0.

5 27. A kit for monitoring gastric emptying, comprising a first marker agent formulated in a delayed-release formulation that prevents said first marker agent from being released at a pH lower than about 6.0, and instructions for using said formulation for determining gastric emptying.

10 28. The kit of claim 27, further comprising a blood collection device.

29. The kit of claim 27, further comprising a composition for detecting the presence of the marker agent.

15 30. The kit of claim 27, further comprising a second marker agent formulated in a formulation that prevents said second marker agent from being released at a pH lower than about 6.0.

31. The kit of claim 30, wherein said second marker agent is formulated in the same delayed-release formulation as said first marker agent.

20 32. The kit of claim 27, further comprising a series of concentrations of marker agent in delayed release formulations for use in producing a standard curve, said formulations each being resistant to release of said marker agent at a pH lower than about 6.0.

33. The kit of claim 32, further comprising a reagent that lowers the pH of the formulation to a pH lower than about 6.0.

25 34. A kit for use in a method of claim 1, said kit comprising a first marker agent formulated in a delayed-release formulation that prevents said first marker agent from being released at pH lower than about 6.0 and instructions for the performance of the assay.

35. The kit of claim 27, further comprising a blood collection device.

36. The kit of claim 27, further comprising a composition for detecting the presence of the marker agent.

37. The kit of claim 27, further comprising a second marker agent formulated in a formulation that prevents said second marker agent from being
5 released at a pH lower than about 6.0.

38. The kit of claim 37, wherein said second marker agent is formulated in the same delayed-release formulation as said first marker agent.

39. The kit of claim 27, further comprising a series of concentrations of marker agent in delayed release formulations for use in producing a
10 standard curve, said formulations each being resistant to release of said marker agent at a pH lower than about 6.0.

40. The kit of claim 39, further comprising a reagent that lowers the pH of the formulation to a pH lower than about 6.0.